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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/948,393	10/10/1997	DENISA D. WAGNER	CFBF-P02-002	6939

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	55

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

08/948393	WAGNER
Examiner: GAMBEL	Art Unit: 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 3/18/03

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 71-73, 77-81, 89-90

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 71-73, 77-81, 89-90

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

PAPER NO. 55

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission, filed on 3/18/03 (Paper No. 52),has been entered.

Applicant's amendment, filed 3/18/03 (Paper No. 53), has been entered.
Claim 71 has been amended.
Claim 90 has been added.

Claims 1-70, 74-76 and 82 have been canceled previously.

Claims 71-73, 77-81 and 83-90 are pending.

Claims 71-73, 77-81 and 83-90 are under consideration as they read on the elected invention, drawn to methods of treating or inhibiting atherosclerosis with PSGL-1, fragments and chimeric constructs thereof.

As pointed our previously, the following of record has been noted.

For examination purposes, the use of PSGL-1, fragments and chimeric constructs thereof have the inherent property of inhibiting L- / E-selectin-mediated interactions. If applicant disagrees with this assessment, then such claims would be removed from consideration as they on the elected invention. Also, analogs of PSGL-1 read on fragments and chimeric constructs thereof.

If applicant disagrees with this assessment, then such claims would be removed from consideration as they on the elected invention

For examination purposes, PSGL "on a leukocyte" (e.g. neutrophil, monocyte) reads on PSGL and not on the administration of cells per se.

It is noted that applicant's amendment, filed 3/18/03 (Paper No. 53), has amended claim 71 to recite "said agent effective to inhibit the interaction between P-selectin and PSGL-1 and between E-selectin and a ligand of E-selectin" and added claim 90 to recite "said agent effective to inhibit the interaction between P-selectin and PSGL-1", which is consistent with the rejections of record.

Claims 71-73, 77-81 and 83-90 as they read on methods of treating or inhibiting atherosclerosis with agents other than PSGL-1 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Again, applicant is invited to provide a complete set of the pending claims for clarity, and preferably applicant is invited to amend or to cancel/add claims as they read on methods of treating or inhibiting atherosclerosis with PSGL-1 for clarity. The pending claims are spread over a number of amendments. Further, the claims have been restricted into Groups.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. This Office Action will be in response to applicant's arguments, filed 3/18/03 (Paper No. 53). The rejections of record can be found in the previous Office Actions (Paper Nos. 44/46/48).

3. Upon reconsideration of applicant's amended claim 71, filed 3/18/03 (Paper No. 53), the previous rejection under 35 U.S.C. 112, first paragraph, enablement has been withdrawn.

4. Claims 71-73, 77-81 and 83-90 are rejected under 35 U.S.C. § 102(e) as being anticipated by Cummings et al. (U.S. Patent No. 5,464,778) (see entire document) for the reasons set forth in the previous Office Actions (Paper Nos. 44/46/48) and addressed herein.

Claims 71-73, 77-81 and 83-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummings et al. (U.S. patent No. 5,464,778) in view of Larsen et al. (U.S. Patent No. 5,840,679) for the reasons set forth in the previous Office Actions (Paper Nos. 44/46/48) and addressed herein.

Applicant's arguments in conjunction with the 1.131 declaration under 37 C.F.R. § 1.131, filed 3/18/03 (Paper Nos. 53/54), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant asserts that the enclosed Declaration by the co-inventors demonstrates that the conception of the instant invention occurred as early as 1988 and that an actual reduction to practice occurred as early as 9/13/93. The time period between 11/16/92 and 9/13/93 was consumed by the development of a knockout mouse model for atherosclerosis and the testing of the mouse model to verify the inventive concept. It is noted that the conclusion of the results of the experiment were collected and analyzed on or about 5/6/94.

Applicant's rely on the statement: " Macrophages eat bits of activated platelets. ELAM-1 = Padgem. Do monocytes bind to Padgem on platelets. Padgem is an opsonizing agent to get rid of debris of platelets." Applicant assert their conception of a functional relationship between E-selectin and P-selectin, and that P-selectin mediates the binding of platelets to macrophages (leukocytes implicated in atherosclerosis).

Applicant relied upon the preparing a P-selectin knock-out mouse to study the role of P-selectin in atherosclerosis by feeding the P-selectin deficient mice with a lipid diet. The results of this study demonstrate a reduction in the size of atherosclerotic lesions in P-selectin deficient mice.

Applicant assert that based upon these results that inhibitors of P-selectin/ligand binding and/or E-selectin/ligand binding would be useful for the treatment or inhibition of atherosclerosis, constituting an actual reduction to practice the claimed invention.

The evidence, submitted is insufficient to establish a reduction to practice of the invention in this country prior to the effective date of the prior art.

The 37 CFR 1.131 declaration must establish possession of either the whole invention claimed or something falling within the claim in the sense that the claims as a whole reads on it. In re Tanczyn 146 USPQ 298 (CCPA 1965). See MPEP 715.02.

Applicant has not overcome the prior art rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the references(s) or the activity.

The test is whether the facts set out in the affidavit are such as would persuade one skilled in the art that the application possessed so much of the invention as is shown in the references. In re Schaub 190 USPQ 324 (CCPA 1976). See MPEP 715.03.

Applicant's evidence of conception and diligence does not address the critical elements of the instant claims which are drawn to a method of treating or inhibiting atherosclerosis in a mammal by administering PSGL-1.

There is insufficient evidence the ordinary artisan would have taken applicant statement: " Macrophages eat bits of activated platelets. ELAM-1 = Padgem. Do monocytes bind to Padgem on platelets. Padgem is an opsonizing agent to get rid of debris of platelets." to establish possession of treating atherosclerosis in a mammal by administering PSGL-1.

Similarly there is insufficient evidence the ordinary artisan would have taken applicant preparation of a P-selectin knock-out mouse to study the role of P-selectin in atherosclerosis by feeding the P-selectin deficient mice with a lipid diet to establish possession of treating atherosclerosis in a mammal by administering PSGL-1.

Further, it is noted that applicant's evidence relies upon experimental animals serves as model systems to selectively investigate different steps of the injury cascade providing specific insights into key mechanisms operating in diseases. While applicant's studies with a P-selectin knockout mouse may have provided insights into the role of P-selectin to atherosclerosis, there is insufficient evidence and correlation of establishing possession of treating atherosclerosis in a mammal by administering PSGL-1, particularly given the absence of any disclosure of administering PSGL-1 in applicant's 131 Declaration and Exhibits.

Also, applicant has not provided objective evidence that applicant was in possession of PSGL-1 itself as well as its use as a therapeutic agent in treating atherosclerosis prior to the disclosure of the prior art. Applicant's reliance on a generic concept of a possible role of P-selectin in atherosclerosis and subsequent findings in an experimental animal model does not support the use of PSGL-1 in treating atherosclerosis.

Absent a clear support or facts are establishing applicant's assertions of conception and diligence (and reduction to practice or subsequent reduction to practice) before the prior art, applicant's arguments are not found persuasive and the rejection is maintained for the reasons of record (e.g., see Paper Nos. 44, 46 and 48).

Again it is noted that Cummings et al. teach the use of PSGL in the treatment of leukocyte adherence, inflammation and coagulation, including ischemia-reperfusion injury and atherosclerosis (see column 18, paragraphs 5-8; columns 19-20, overlapping paragraph).

Therefore, applicant's arguments are not found persuasive for the reasons of record.

5. Claims 71-73, 77-81 and 83-90 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over
claims 40-41, 45, 49-52, 56, 59-60, 73-74 (or appropriate pending claims) as they read on the use of PSGL-1 to treat atherosclerosis of copending application Serial No. 09/436,076 and
claims 39-88 (or appropriate pending claims)as they read on the use of PSGL-1 to treat atherosclerosis of copending application USSN 09/883,642 for the reasons of record set forth in Paper Nos. 44/46/48.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same or nearly the same methods of treating atherosclerosis with the same or nearly the same PSGL-1, fragments and chimeric constructs thereof.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's amendment, filed 3/18/03 (Paper No. 53), indicates that applicant is prepared to file a terminal disclaimer in this application to overcome this rejection provided that the application is otherwise considered to be in proper condition for allowance.

6. No claim is allowed

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
June 13, 2003